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Are current credentialing requirements for robotic surgery adequate to ensure surgeon proficiency?

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Abstract

Background Robotic surgery has seen unprecedented growth, requiring hospitals to establish or update credentialing policies regarding this technology. Concerns about verification of robotic surgeon proficiency and the adequacy of current credentialing criteria to maintain patient safety have arisen. The aim of this project was to examine existing institutional credentialing requirements for robotic surgery and evaluate their adequacy in ensuring surgeon proficiency.

Methods Robotic credentialing policies for community and academic surgery programs were acquired and reviewed. Common criteria across institutions related to credentialing and recredentialing were identified and the average, standard deviation, and range of numeric requirements, if defined, was calculated. Criteria for proctors and assistants were also analyzed.

Results Policies from 42 geographically dispersed US hospitals were reviewed. The majority of policies relied on a defined number of proctored cases as a surrogate for proficiency with an average of 3.24 ± 1.69 and a range of 1–10 cases required for initial credentialing. While 34 policies (81%) addressed maintenance of privileges requirements, there was wide variability in the average number of required robotic cases (7.19 ± 3.28 per year) and range (1–15 cases per year). Only 11 policies (26%) addressed the maximum allowable time gap between robotic cases.

Conclusion Significant variability in credentialing policies exists in a representative sample of US hospitals. Most policies require completion of a robotic surgery training course and a small number of proctored cases; however, ongoing objective performance assessments and patient outcome monitoring was rarely described. Existing credentialing policies are likely inadequate to ensure surgeon proficiency; therefore, development and wide implementation of robust credentialing guidelines is recommended to optimize patient safety and outcomes.

Keywords Robotic surgery · Credentialing · Privileges · Patient safety

Robotic surgery has seen exponential growth over the past two decades, with routine use of robotic surgical devices now common in many surgical specialties [1]. Approximately 644,000 robotic procedures were performed in the USA in 2017, an increase of 29% from 2 years prior [2]. In general surgery alone, 246,000 procedures were performed using a robotic system, an increase of 75% from 2015 [2]. To keep up with this trend, hospitals have adopted or updated credentialing policies pertaining to robotic surgery. While the Joint Commission requires institutions have specific policies related to credentialing to maintain safe and competent patient care, the specific qualifications remain under institutional purview [3]. As a result, there is significant variability in credentialing processes. A small-scale survey of 11 surgeons conducted by the Food and Drug Administration in 2013 revealed a lack of standardization in the credentialing processes at their respective institutions [4, 5].

Variability in critical aspects of credentialing may result in a lack of universal verification of surgeon proficiency, which may ultimately lead to compromised patient safety. Importantly, credentialing criteria typically rely on surgeon certification by their governing bodies. For example, the American Board of Surgery (ABS) and American

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Board of Obstetrics and Gynecology (ABOG) require Fundamentals of Laparoscopic Surgery (FLS) certification prior to graduation from residency [6, 7]. As a consequence, surgical trainees have to demonstrate proficiency in basic laparoscopic skills before they graduate, which ensures an appropriate level of skill in laparoscopy. Unfortunately, the same is not true for robotic surgery. Despite the existence of the Fundamentals of Robotic Surgery (FRS), a robust assessment platform for basic robotic skills that was developed and validated by a multidisciplinary group, demonstration of proficiency in robotic surgery is not currently a requirement for certification of surgeons [8]. Given this vacuum, surgeons rely on completion of industry-sponsored certification courses that have attracted criticism [4, 9]. It is therefore not surprising that recent lawsuits have argued that institutional robotic surgery credentialing processes are not sufficient to ensure patient safety [10].

The aim of this project was to examine institutional credentialing requirements for robotic surgery and evaluate their adequacy in ensuring surgeon proficiency. As robotic surgical devices become more widely available, a critical appraisal of current robotic credentialing policies in US hospitals is necessary to identify areas of concern and develop more proficiency-based guidelines for future robotic credentialing.

Materials and methods

Robotic credentialing policies for community and academic surgery programs were acquired via personal request to centers with high-volume robotic surgeons and through an open request via social media to a network of robotic surgeons. IRB approval was not required for this study. A manifest content analysis, which takes a quantitative approach to qualitative material, was performed to quantitatively assess the policies [11]. Following guidelines for manifest content analysis, an inductive preliminary review of received policies identified common criteria used across institutions for initial credentialing and recredentialing [12, 13]. A coding spreadsheet was created to document the presence or absence of common elements of the different robotic policies, including a code for unique or miscellaneous items.

Codes fell into five general domains and were as follows:

Demographic/descriptive details of the program

Name and location of institution, program setting (university or community), and the year of policy creation or most recent revision of the policy.

Basic credentials required of all practitioners

Accreditation Council for Graduate Medical Education (ACGME)/American Osteopathic Association (AOA) training program completion requirement, board certified/board eligible requirement, existing privileges for equivalent open/minimally invasive surgery (MIS) procedures, and the maximum amount of time allowed after completion of robotic training to first proctored case.

Credentialing requirements based on pathway (new robotic surgeon, recent graduate with robotic training, or transferring surgeon with robotic experience at previous institution)

New robotic surgeon pathway (i.e., practicing surgeon seeking robotic privileges)

Robotic training course documentation, simulation score requirement, need for cadaveric/animate laboratory component to course, observation/assist case requirements, and required number of proctored cases.

Recent graduate having completed robotic training pathway

Maximum allowable time after graduation from residency/fellowship until application for privileges, case log requirements, need for a program director letter, and required number of proctored cases.

Transferring robotic surgeon pathway

Minimum case requirements, privileges documentation, need for a letter from previous department chairperson, and required number of proctored cases.

Outcome tracking and maintenance of privileges requirements

Focused Professional Practice Evaluation (FPPE), Maintenance of Privileges (MOP) minimum case volume per unit time including requirements if surgeon falls below MOP volume, and the maximum allowable robotic case time gap limit.

Other criteria

Definition or number of cases required to become a proctor, credentials required to become a robotic assistant, MOP volume for assistants, and whether there was a distinction between basic and advanced robotic procedures.

Policies were subsequently assessed in detail according to the created rubric. The number of policies addressing each unique policy component was recorded and the total percentage of policies referencing each component was calculated. If present, numeric data such as specific case volume requirements were recorded as well. The average, standard deviation, and range of the reported numbers were calculated.

Results

Demographic/descriptive details of the program

Robotic credentialing policies from 42 institutions (18 university and 24 community-based hospitals) from 24 different states across the country were received and reviewed. While all reviewed policies were active, the median year of the most recent iteration of the policies was 2017 (range 2008–2019) for the 16 policies (38%) with reported dates of creation or revision.

Basic credentials required of all practitioners

When assessing the basic credentials required of all surgeons applying for robotic privileges, 16 policies (38%) required applicants to have completed an ACGME/AOA accredited residency program, and 25 policies (60%) required that the surgeon be board certified or board eligible. Thirty-five policies (83%) explicitly stated that surgeons must have privileges for the equivalent open or minimally invasive procedures for which they are applying for robotic privileges. Only 6 policies (14%) defined the maximum amount of time allowed after completion of robotic training to first proctored case (mean 3.50 ± 4.32 months, range 1–12 months).

Credentialing requirements based on pathway

Of 34 policies (81%) with a numeric proctored case requirement, 28 policies (67%) had a constant requirement for all pathways and 6 policies (14%) had tiered proctoring requirements based on previous robotic experience (Table 1). Generally, if there was a distinction based on previous robotic experience, the requirement for experienced surgeons lowered to one proctored case; however, one program did not require any proctoring for surgeons transferring with a case volume of > 50 robotic cases per year.

New robotic surgeon pathway

Forty (95%) policies required documentation of a completed robotic surgery training course, but only 13 policies (31%) detailed the required minimum course hours (Table 1). Thirteen policies (31%) specified that training courses must have a cadaveric or animate laboratory component. Twelve policies (29%) required a simulation component to the course, but only 9 policies (21%) specified a minimum passing score (Table 1). Twenty-three policies (55%) required surgeons to either observe or assist a robotic case prior to advancing to proctored cases; however, only 16 policies (38%) defined the number of case observations or assisted robotic cases required (Table 1). Thirty-four policies (81%) defined the number of proctored cases required for newly trained robotic surgeons (Table 1).

Table 1 Credentialing requirements based on pathway

Policy pathway	Credentialing requirement	Policies with numeric requirement (% of total policies)	Mean ± SD	Range (units)
New robotic surgeons	Minimum robotic course hours	13 (31%)	5.31 ± 3.84	3–16 h
	Minimum simulation passing score	9 (21%)	86.11 ± 6.97	70–90%
	Observe/assist robotic cases	16 (38%)	2.25 ± 1.18	1–6 cases
	Required number of proctored cases	34 (81%)	3.24 ± 1.69	1–10 cases
Recent trainees with robotic experience	Definition of “recent”	8 (19%)	20.25 ± 10.61	12–36 months
	Minimum number of previous robotic cases	11 (26%)	13.15 ± 5.74	5–24 cases
	Required number of proctored cases	29 (69%)	2.93 ± 1.79	1–10 cases
Transferring robotic surgeons	Minimum number of previous robotic cases per 12 months	18 (43%)	10.72 ± 4.28	5–20 cases
	Required number of proctored cases	27 (64%)	2.63 ± 1.82	1 – 10 cases

Data reported as mean ± standard deviation (SD) and range. Percentages rounded to the nearest whole number

Recent graduate having completed robotic training pathway

The definition of a recent trainee was described in 8 (19%) of the robotic credentialing policies as a surgeon who graduated residency or fellowship less than 3 years prior to application for robotic privileges (Table 1). Twenty-two policies (52%) required a letter from the surgeon's residency or fellowship program director detailing robotic training. Twenty-three policies (55%) required surgeons to provide a robotic case log, but only 11 policies (26%) specified required total robotic case numbers (Table 1). Twenty-nine policies (69%) defined the number of proctored cases required for recent trainees (Table 1).

Transferring robotic surgeon pathway

For surgeons with previous robotic privileges in another hospital system, 14 policies (33%) required a letter from the Chair of the Department of Surgery of the surgeon's previous institution verifying the surgeon's ability to perform robotic surgery. Seven policies (17%) required documentation of the surgeon's robotic privileges held at the previous institution. Twenty-eight policies (67%) required documentation of previous robotic case experience (i.e., submission of robotic case log or provision of top 10 robotic case codes with case numbers). Twenty-three policies (55%) required a specified minimum number of robotic cases be provided for review but only 18 (43%) required documentation of volume per unit time (Table 1). Twenty-seven policies (64%) defined the number of proctored cases required for surgeons with previous robotic experience (Table 1).

Outcome tracking and maintenance of privileges requirements

Twenty (48%) policies made reference to a FPPE; one policy (2%) was time-based (6 months) and the remaining 19 (45%) were case-based (mean 5.84 cases $\pm$ 2.27, range 2–10 cases), with the FPPE beginning after the required proctored cases. Only 5 policies (12%) referenced an initial period of provisional privileges and the steps required for a surgeon to progress to unrestricted robotic privileges was rarely well-described.

Thirty-four policies (81%) addressed MOP requirements with the recredentialing cycle running on a 12- or 24-month basis. The average number of robotic cases for MOP when adjusted to a 12-month cycle was 7.19 $\pm$ 3.28 cases per year with a range of 1–15 cases per year. Twenty-three policies (55%) mentioned a plan if the surgeon fell below the expected robotic case volume: 14 policies (33%) required simulation time, 13 policies (31%) required further proctoring, and 8 policies (19%) required a FPPE plan. Only 11 (26%) of the policies addressed a maximum allowable gap between robotic cases. A prolonged gap would trigger either further simulation or proctoring before regaining unrestricted robotic privileges. The average maximum allowable gap in robotic cases was 5.00 $\pm$ 2.83 (range of 1–12) months.

Other criteria

Although the majority of the policies had a proctoring requirement, only 15 policies (36%) included a definition for "proctor". Two policies (5%) only required a proctor must be "sufficiently qualified" or "in good standing". Of the 13 policies (31%) which provided a minimum volume for proctors, the mean was 30.00 $\pm$ 13.84 (range 5–50) robotic cases. Seven policies (17%) defined who could serve as a robotic assistant, and only 3 policies (7%) provided a MOP volume requirement for robotic assistants (mean 6.33 $\pm$ 1.53, range 5–8 cases per 12 months).

Twelve policies (29%) distinguished between basic and advanced robotic cases. Of those policies, only 6 (14%) defined the number of basic robotic cases to be completed prior to progression to advanced privileges (mean 14.17 $\pm$ 5.85, range 10–25 basic cases). No reviewed policy required operating room team training as part of robotic credentialing.

Discussion

Significant variability in robotic credentialing requirements was seen in 42 policies reviewed from institutions across the USA. Using an inductive approach, we were able to identify common and unique aspects of current credentialing requirements for evaluation. In 2006, an international consensus group of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the Minimally Invasive Robotic Association (MIRA) provided guidelines for institutions granting privileges in therapeutic robotic procedures [9]. Several aspects of the reviewed policies aligned with the SAGES-MIRA recommendations including documentation of previous robotic experience for recent trainees and training requirements for new robotic surgeons (i.e., completion of a robotic training course, need for a hands-on course component, case observation, and proctored cases) [9]. Conversely, the guidelines suggested aspects that were not seen in many institutional policies such as required training for operative staff and technical support team, a period of provisional privileges after initial credentialing, performance outcomes monitoring, and an appeal processes for surgeons who have been denied privileges [9]. Aspects of reviewed policies not included in the SAGES-MIRA guidelines were requirements for transferring robotic surgeons, robotic case gap limits, and proctoring and assistant requirements. While we were unable to determine whether institutions utilized the

SAGES-MIRA guidelines during development of their credentialing policies, the majority of policies reviewed were developed after the publication of these guidelines. Despite these available recommendations, significant gaps and variability in robotic credentialing policies still exist.

Importantly, the SAGES-MIRA consensus group guidelines state that "surgical proficiency should be assessed for every surgeon, and privileges should not be granted or denied solely based on the number of procedures performed" [9]. Despite this recommendation, most of the reviewed policies relied on defined case numbers as a surrogate for proficiency. This was true for initial credentialing, maintenance of privileges, and proctoring. In a systematic review of the literature examining the learning curve for robotic surgery, the number of robotic cases needed to reach a performance plateau varied widely, with a range of 19–128 cases for colorectal surgery and a range of 8–95 cases for foregut surgery, with a median of 25 cases for both procedures [14]. As the maximum number of proctored cases required by any policy in this study was 10 cases, the need for institutions to revisit proctoring requirements and to consider other methods to verify surgeon proficiency becomes apparent.

Notably, there was an almost universal reliance on industry-sponsored robotic training courses with 40 (95%) policies requiring documentation of completion of such a course. While such courses cover the existing vacuum in robotic surgery training and certification and help surgeons improve their robotic skill, related ethical and legal concerns have also been raised [9, 10, 15].

Perhaps the most troubling result of this study is the lack of outcome monitoring for newly credentialed robotic surgeons, despite inclusion in the SAGES-MIRA guidelines [9]. Less than half of the policies referenced a FPPE for newly credentialed robotic surgeons operating independently, and specific patient outcome monitoring was rarely described. Similarly concerning were 1, the majority of credentialing policies lacked a defined gap limit in robotic cases; and 2, the low MOP volume required by many institutions. In one study, degradation of robotic surgical skills of newly trained surgeons demonstrated a significant skill decay after only 4 weeks of inactivity [16].

A limitation of our study was that it was based on a nonrandomized sample of credentialing policies from across the USA which introduces sampling bias. In addition, nonresponse bias may have also affected our results as surgeons from institutions with poorly detailed policies may have deemed them inadequate for external review and refrained from submitting their policies. Further, given that the request for policies was sent to high-volume robotic surgeons and via a national network of robotic surgeons, the received policies may over represent more established US robotic surgery programs. However, due to the wide geographic distribution and relatively equal representation from community and academic intuitions, we believe that it is otherwise an adequate approximation of US robotic surgery credentialing policies.

Overall, reviewed credentialing policies were too vague to appropriately guide decisions on surgeon proficiency with robotic surgery. This lack of detail in policies reviewed may be related to the lack of specific recommendations in existing guidelines. In order to ensure robotic surgeon proficiency and optimize patient safety and outcomes, the development and wide implementation of specific and detailed robotic surgery credentialing guidelines is recommended.

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Compliance with ethical standards

Disclosures Dr. Rosen has given talks and led courses sponsored by Intuitive Surgical. Dr. Levy is the Interim Executive Director at the Institute for Surgical Excellence (ISE), a 501(c)(3) public charity. Dr. Martino is a patient safety consultant for Intuitive Surgical, Medtronic, and Ethicon as well as an educator for GlaxoSmithKline and a peer reviewer for UpToDate. Dr. Stefanidis has received a research grant from ExplORer Surgical for unrelated work. Dr. Huffman has no conflicts of interest or financial ties to disclose.

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